DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

August 14, 2000

Our Reference: 2945038
Richard W. Howse, President
All Seas Wholesale, Inc.
2414 San Bruno Avenue
San Francisco, CA 94134

WARNING LETTER

Dear Mr. Howse:

On May 24 and 25, 2000, we inspected your seafood processing facility, All Seas Wholesale Inc., located at 2414 San Bruno Avenue, San Francisco, California. We conducted this inspection to determine compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your histamine forming fish and refrigerated vacuum packed fish and fishery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. We attached a copy of the FDA 483 for your reference. Your serious HACCP violations are as follows:

1. You must have a written HACCP plan to control any food safety hazards that are likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have HACCP plans for refrigerated vacuum packed raw fish and smoked salmon, to control the food safety hazards of pathogen growth and *Clostridium botulinum* toxin formation as a result of time/temperature abuse.

2. You must have a HACCP plan that lists the critical control points, in order to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for scombroid fish does not list the critical control point (CCP) of refrigerated storage for controlling the food safety hazard of histamine formation as a result of time and temperature abuse.

Further district review of your HACCP plan for scombroid fish revealed the following deficiency:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). However, your firm's HACCP plan for scombroid species does not identify a critical limit at the receiving CCP that is adequate to control the hazard of histamine formation as a result of temperature abuse during transport. Examples of adequate critical limits at receipt for your HACCP plan might include either: (a) presence of adequate ice or other cooling agent at time of delivery; or (b) the shipment is accompanied by transportation records showing that the fish was held at or below 40° Fahrenheit throughout transit.

At the end of the previous inspection we discussed with you similar inspectional observations, which we listed on Form FDA 483. You verbally promised to correct the problems. These HACCP deficiencies were also repeated to you by correspondence from this office on August 31, 1999. Our recent inspection shows that your firm did not correct all of the HACCP deficiencies that we cited in our previous letter.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure and/or injunction.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,

Mary Woleske

Mary H. Woleske
Acting District Director
San Francisco District

Attachment